Paper No. **208**

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ELI **LILLY** AND COMPANY
(U.S. Application 08/508,434),

Junior Party,

v.

KIMBERLY O. **CAMERON**, PAUL DA SILVA-JARDINE, ERIC R. LARSON,
JAMES R. HAUSKE and ROBERT L. ROSATI
(U.S. Application 08/628,605),

Senior Party.

Patent Interference No. 104,101

Before: SCHAFER, GARDINER-LANE and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

FINAL JUDGMENT ON PRIORITY

This interference is before a merits panel for a decision on priority. The parties were provided an opportunity to present arguments at a final hearing. The parties, however, indicated that while they were available for such a hearing, they did not require one.

I. Summary of the Decision

In its broadest sense, this interference is directed to a compound. Lilly, as junior party, has attempted to prove an earlier actual reduction to practice of the compound of the count. A party seeking to establish an actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment that met every requirement of the interference count, and (2) the embodiment operated for its intended purpose. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000). As the count is directed to a compound without a stated utility, a substantial utility for any purpose is sufficient to show that the compound operated for its intended purpose. *Campbell v. Wettstein*, 476 F.2d 642, 649, 177 USPQ 376, 381 (CCPA 1973).

Lilly has submitted numerous alleged compounds that are said to fall within the scope of the count. Yet, Lilly has identified only one particular compound (LY 311583) as having a recognized substantial utility. As to compound LY 311583, Lilly has failed to sufficiently demonstrate that they constructed a compound having the LY 311583 structure.

Lilly, as junior party, has failed to meet its burden of proof. Priority of invention for Count 2, the sole count in interference, is awarded against junior party Lilly.

II. Findings of Fact

A. Previous Findings

1. Real Parties in Interest

F1. Lilly is the real party in interest in Lilly ‘434 which was filed on July 31, 1995. Pfizer is

the real party in interest in Cameron ‘605 which was filed on July 1, 1996.

2. Accorded Priority Benefit Dates

i. Senior Party

F2. Cameron ‘605 was filed on July 1, 1996. Solely for purposes of priority, Cameron ‘605 has been accorded benefit of the filing dates of:

a. PCT Application PCT/IB94/00282 filed on September 13, 1994; and

b. U.S. Application 08/135,386 filed on **October 12, 1993**, now abandoned.

(Paper No. 1, p. 41; Paper No. 54, p. 7).

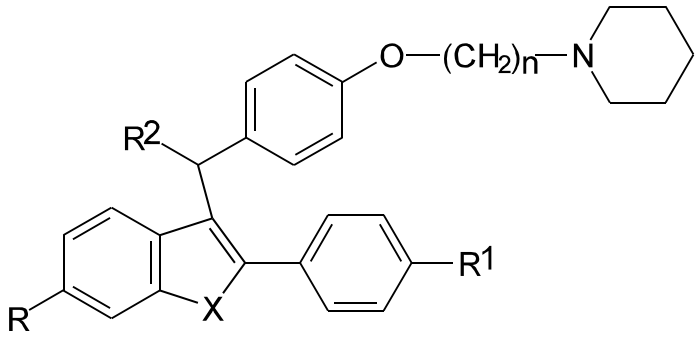
ii. Junior Party

F3. Lilly ‘434 was filed on July 31, 1995 naming Henry U. Bryant, George J. Cullinan, Jeffrey A. Dodge, Kennan J. Fahey and Charles D. Jones as inventors. Solely for purposes of priority, Lilly ‘434 has been accorded the benefit of the filing date of U.S. Application 08/309,301 (Lilly ‘301) filed on **September 20, 1994**. (Notice Redeclaring Interference, Paper No. 177, p. 3). Lilly ‘434 is said to be a divisional of Lilly ‘301. (Lilly ‘434 specification, p. 1).

3. The Count and Corresponding Claims

F4. Count 2 is the sole count in the interference and reads as follows:

Count 2: The compound having Formula (1):



Formula (1)

wherein

R is –OH,
R^1 is –OH,
R^2 is –H,
n is 2 or 3 and
X is sulfur,

or

a pharmaceutically acceptable salt of a compound having Formula (1),

or

a pharmaceutical composition comprising a compound having Formula (1) or a pharmaceutically acceptable salt thereof.

(Paper No. 54, pp. 4-5 and Paper No. 60, p. 2, Paper No. 177, p. 5).

F5. The claims of the parties are:

Lilly 08/508,434:	1-24 and 46-65
Cameron 08/628,605:	8, 12-15, 17-18, 42-69, 81, 87 and 97

The claims of the parties that correspond to Count 2 are:

Lilly 08/508,434:	1-7, 21-22, 46, 50 and 54
Cameron 08/628,605:	42 and 66

The claims of the parties that do not correspond to Count 2 are:

Lilly 08/508,434:	8-20, 23-24, 47-49, 51-53 and 55-65
Cameron 08/628,605:	8, 12-15, 17-18, 43-65, 67-69, 81, 87 and 97

(Paper No. 177, p. 5).

B. Additional Findings

F6. Lilly allegedly made numerous compounds that fall within the scope of Count 2. With the exceptions of Lilly Compounds 311583 and 125001, Lilly has failed to sufficiently identify evidence that the allegedly manufactured compounds were tested to establish a practical, recognized utility.

1. Lilly Compound 125001

F7. Mr. Magee testified that during the period of 1992 to 1994 he was an Associate Biologist working in the In Vivo Pharmacology Laboratory of the Skeletal Research Division under the supervision of Dr. Henry Bryant, a named inventor of the involved Lilly '434 application. (Declaration of David E. Magee, EX 1156, ¶ 4).

F8. Mr. Magee has testified that:

> Between August 22-26, 1992, our lab performed an analysis of the biological activity of compounds including a compound with serial number LY 125001. This experiment was designated B62. The protocol set-up is recorded on page 46 of Research Notebook W53-ANR issued to Harlan Cole (Exhibit 1234, Bates No. 3221). Control groups were administered 1% carboxymethylcellulose or α 17-ethynyl estradiol (EE_2) (Sigma Chemical CO., St. Louis, MO) in suspension in 1 % carboxymethylcellulose. Test compounds were administered orally in suspension in 1% carboxymethylcellulose to groups of ovariectomized rats from

August 22-26. The rats were sacrificed and measurements including blood serum cholesterol concentration were analyzed.

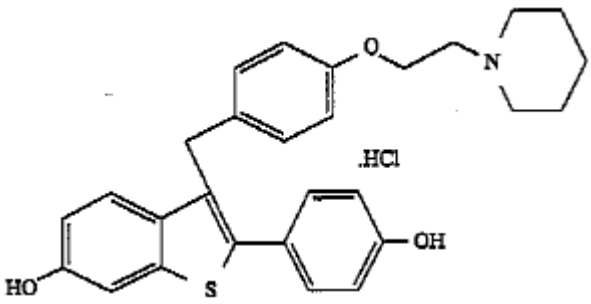
(EX 1156, ¶ 12).

F9. Mr. Magee did not testify as to the structure of the LY 125001 compound.

F10. Lilly has failed to sufficiently identify the structure of compound 125001. Additionally, Lilly has failed to sufficiently identify evidence that an inventor or agent thereof appreciated that the biological activity tests established the usefulness of compound 125001.

2. Lilly Compound 311583

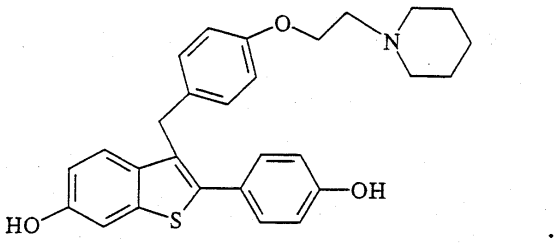
F11. Lilly compound 311583 is said to have the following structure:



(EX 1216). The compound depicted above falls within the scope of Count 2, the sole count in interference.

George Cullinan's Testimony

F12. Lilly inventor George Cullinan testified that prior to May 1992, Dr. Charles Jones, also a Lilly inventor, suggested that Mr. Cullinan investigate a compound having the following structure:

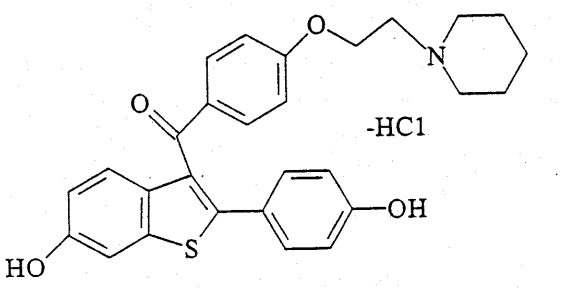


(EX 1152, ¶¶ 14-15).

F13. Mr. Cullinan testifies that, after conducting a reaction, he normally submitted samples of the product to Lilly's Physical Chemistry Laboratory for testing. (EX 1152, ¶ 23). Upon completion of the testing, a Lilly technician would provide Mr. Cullinan with "a printout of the results of the test(s)." (EX 1152, ¶ 23). Lilly has failed to direct our attention to where a copy of these printouts may be found in the record. Moreover, Lilly has failed to explain whether the data in the "printouts" is accurately reflected in Mr. Cullinan's notebook or Lilly's Physical Chemistry ("PC") submission requests.

b. Mr. Cullinan's Notebook Page 53

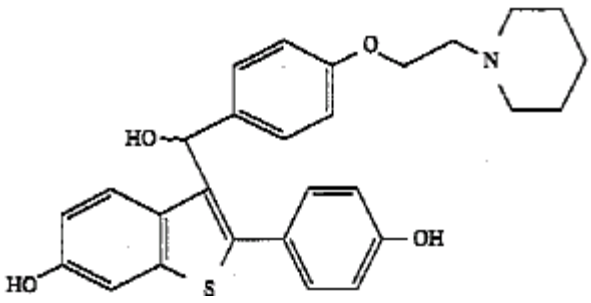
F14. Mr. Cullinan testifies that on June 2, 1992, he entered into page 53 of his notebook C12-AMF (CX 1201) a proposed chemical reduction of a compound having the following structure:



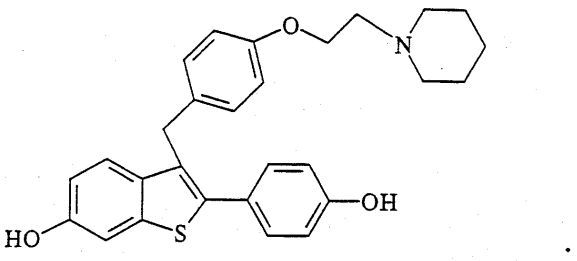
(Paper No. 202, p. 26, LX 1152, ¶ 30).

F15. Mr. Cullinan testifies that he forwarded a request for mass spectroscopy analysis and proton NMR analysis to Lilly's Physical Chemistry lab. This request was given the submission number PC 455,899. (Paper No. 202, p. 27, LX 1152, ¶ 31).

F16. According to Mr. Cullinan and Lilly, the mass spectroscopy and proton NMR analysis helped to confirm that he made a mixture of compounds having the formula:



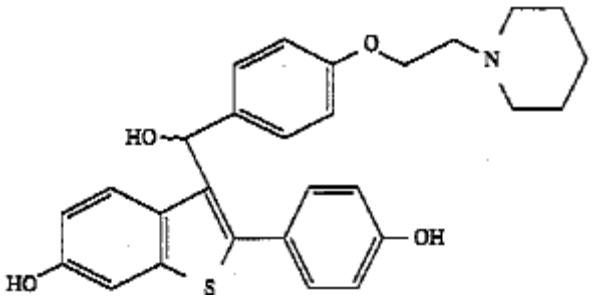
and



(Paper No. 202, pp. 27-28, LX 1152, ¶ 31). The second depicted structure falls within the scope of Count 2.

Cullinan Notebook Page 261

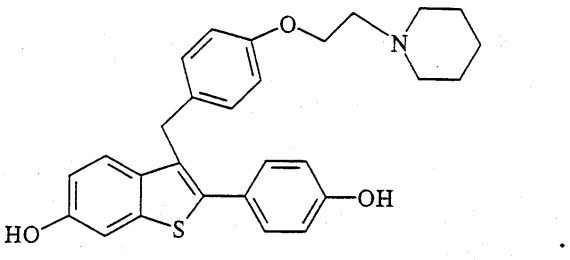
F17. Mr. Cullinan testifies that on March 11, 1993 he entered on page 261 of his notebook a proposed chemical reduction of a compound having the following formula:



F18. Mr. Cullinan stated that the reduction was performed by mixing 710 mg of the above compound with 210 mg of Et_3SiH, 12 mL TFA and 25 mL DCM. This reduction is said to have yielded 500 mg of product. (EX 1152, ¶ 33).

F19. Mr. Cullinan's testimony fails to specifically identify the source of the starting material, i.e., the "hydroxy" compound that is said to undergo reduction. Moreover, Mr. Cullinan's testimony fails to specifically explain how he confirmed the structure of the starting material undergoing reduction.

F20. Mr. Cullinan testifies that he submitted the product from the above chemical reduction reaction, described on page 261 of his laboratory notebook (EX 1201, Bates No. 3012) for mass spectroscopy analysis, proton NMR analysis and I.R. analysis. (EX 1152, ¶ 34, EX 1211, Bates No. 3069). Mr. Cullinan states that the results of these analyses helped confirm that he had made a compound having the following structure:



(EX 1152, ¶ 34). The above depicted structure is within the scope of Count 2.

F21. Mr. Cullinan's testimony fails to explain how the "mass spectroscopy analysis, proton NMR analysis and I.R. analysis helped to confirm" that he had made the identified compound. Specificlly, Mr. Cullinan failed to cite and/or explain the underlying data for his conclusion that he made the specific structure depicted on PC 469,307 (Bates No. 3069). Additionally, Mr.

Cullinan failed to explain how he had confirmed the identity of the specific hydroxy compound being reduced.

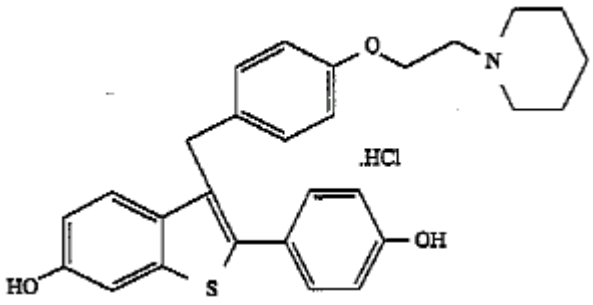
F22. Cullinan laboratory notebook page 261 fails to state the source of the compound undergoing reduction and does not provide a reasonable basis to conclude that the depicted starting material structure is correct.

F23. Cullinan laboratory notebook page 261 contains notations indicating that an NMR and mass spectroscopy were run. Specifically, the notebook page has notations such as "NMR good" and "MS m/e=460." The notebook page notations, however, fail to confirm that the structures depicted in Mr. Cullinan's testimony and in his laboratory notebook are correct. For example, the NMR notation lacks specificity and the mass spectroscopy notation is consistent with a variety of structures falling outside the scope of the count.

Top Half of Cullinan Notebook Page 266 Dated March 17, 1993

F24. Mr. Cullinan testifies that on March 17, 1993 he entered on page 266 of his laboratory notebook (EX 1201, Bates No. 3013) a process for preparing the product obtained on page 261 of his notebook (EX 1201, Bates No. 3012). (EX 1152, ¶ 35). A compound said to have been made by this process was submitted for proton NMR analysis and elemental analysis. (EX 1211, Bates No. 3070). Mr. Cullinan states that the "proton NMR analysis and elemental analysis helped to

confirm" that he had prepared a compound depicted on page 266 of his notebook, which has the following structure:



(EX 1152, ¶ 36). Laboratory notebook page 266 has the number "311583" written next to the above depicted structure.

F25. Mr. Cullinan has failed to explain how the "proton NMR analysis and the elemental analysis helped to confirm" that he had made the compound depicted on page 266 of his notebook. Specifically, Mr. Cullinan has failed direct our attention to the underlying proton NMR data and explain how that test data would support a conclusion that he had prepared the identified structure.

F26. The March 17 portion of Mr. Cullinan's laboratory notebook page 266 depicts the chemical structure Mr. Cullinan is said to have prepared and contains the notation "NMR: O.K."[1] (EX 1201, Bates No. 3013). The notebook page fails to identify the underlying data for the proton NMR analysis.

[1]We understand "NMR" to mean nuclear magnetic resonance.

F27. The March 17 portion of laboratory notebook page 266 also contains notations that would appear to be elemental analysis results. Mr. Cullinan's testimony fails to explain how the elemental analysis notations in his notebook demonstrate that he produced the depicted structure as opposed to a different compound having the same empirical formula. Moreover, the elemental analysis notations are consistent with compounds having the same empirical formula as the depicted structure but falling outside of the count.

Bottom Half of Cullinan Notebook Page 266

F28. According to Mr. Cullinan, on March 22, 1993 he entered onto page 266 of his notebook (EX 1201, Bates No. 3013) a process for further preparing the March 17, 1993 product. Mr. Cullinan testifies that he conducted the described reaction process and formed 330 mg of product. (EX 1152, ¶ 37). On March 23, 1993, Mr. Cullinan is said to have sent this product for mass spectroscopy analysis and elemental analysis. (EX 1211, Bates No. 3071). Mr. Cullinan states that the results of the analyses "helped to confirm" that he made a compound having the structure depicted on page 266 of his notebook. (EX 1152, ¶ 38).

F29. Mr. Cullinan has failed to explain how the "mass spectroscopy analysis and the elemental analysis helped to confirm" that he had made the compound depicted on page 266 of his notebook.

F30. The March 22 portion of Mr. Cullinan's laboratory notebook page 266 depicts the chemical structure Mr. Cullinan is said to have prepared and contains notations consistent with mass spectroscopy analysis ("MS m/e=460") and elemental analysis. Yet, the notations contained on page 266 do not conclusively demonstrate that Mr. Cullinan produced the specifically identified structure. Specifically, these notations are consistent with compounds having the same empirical formula as the depicted structure but falling outside of the count.

F31. Mr. Cullinan testifies that he submitted a submission sheet (Exhibit 1216, Bates No. 3114) to the Research Records Department that requested a serial number for the product of the reaction described on page 266 of his notebook. The compound is said to have been given the Serial Number 311583. (EX 1152, ¶ 39).

Lilly Physical Chemical Laboratory Submission Sheets 469307, 469590 and 469823

F32. Ms. Susan M. Sharples is a Physical Chemist employed by Lilly. (EX 1160, ¶ 2). Ms. Sharples testified that she has worked in the Physical Chemistry Laboratory Department from May 1984 to the present. (EX 1160, ¶ 2). Ms. Sharples has testified that the physical chemistry submission sheet requests 469307, 469590 and 469823 are true and accurate copies of those contained in Physical Chemistry microfilm archives. (EX 1160, ¶ 6).

F33. The physical chemistry submission sheet documents bear Mr. Cullinan's name and depict the structures depicted on pages 261 and 266 of Mr. Cullinan's notebook. (Sheet 469307, EX

1211, Bates No. 3069; Sheet 469590 and 469823). Specifically, each of the submission sheets depicts the structure of the compound that Mr. Cullinan believed that he had produced. Each submission sheet bears a notation that corresponds to the specific notebook page identified by Mr. Cullinan.

F34. Physical chemistry submission sheet 469307 contains the number "459" next to the notation "M.S."[2] Submission sheet 469823 contains the number "460 " next to the notation "M.S." Moreover, submission sheets 469590 and 469823 both contain what appears to be elemental analysis results. These notations and the data they represent fail to confirm that the depicted structure was the specific structure tested. Simply put, the data conforms to a variety of structures and is not limited to the depicted structure.

Lilly Research Record Submission Sheet for Compound Serial No. 311583

F35. Mr. F. William Bell is an Assistant Senior Chemist at Lilly. (EX 1159, ¶ 2). Mr. Bell has worked in Lilly's Research Records Department from April 1991 to the present. (EX 1159, ¶ 2). Mr. Bell testified that the Serial No. 311583 submission sheet is a true and accurate copy obtained from the Research Records microfilm archive. (EX 1159, ¶ 7).

[2]We understand the notation "M.S." to refer to mass spectroscopy.

F36. Lilly has provided the panel with a copy of the Lilly Submission Sheet for Serial No. 311583. (EX 1216, Bates No. 3114). The submitted copy is difficult to read. For example, the submission sheet contains the notation "Insuff. Mat." next to an illegible typeprint.

F37. The Serial No. 311583 submission sheet depicts the same structure as that depicted on page 266 of Mr. Cullinan's notebook. Similarly, the submission sheet contains the lot no. C12-AMF-266, and twice mentions Mr. Cullinan name. The 311583 submission sheet, like page 266 of Mr. Cullinan's notebook, contains the following notations: 1) "$C_{28}H_{29}NO_3S \bullet HCl$" (the empirical formula for the depicted structure); 2) "496.07" (the molecular weight of the depicted compound); and 3) "330 mg" (the alleged amount of product formed by Mr. Cullinan). Moreover, the submission sheet refers to the dates "17 March 93" and "1 April 93."

F38. The submission sheet fails to demonstrate that Mr. Cullinan produced the depicted structure. The submission sheet does not appear to contain any data from any of the analytical tests said to be requested by Mr. Cullinan. At best, the legible portions of the submission sheet indicate that the depicted compound has a molecular weight of 496.07 and has the empirical formula $C_{28}H_{29}NO_3S \bullet HCl$. Even if the information in these notations was correct, the compounds are not limited to the specific structure depicted. Furthermore, the record is unclear as to whether the stated molecular weight and empirical formula are the expected values based on the depicted structure or whether they represent the results of the tests said to have been requested by Mr. Cullinan.

Testimony of Clifford Paicely

F39. Clifford Paicely has been continuously employed at Lilly as a Senior Laboratory Technician since 1981. (EX 1158, ¶ 2). As part of Mr. Paicely's employment, he conducts mass spectroscopy analyses of chemical compounds that are submitted to him by Lilly chemists. (EX 1158, ¶ 3). Generally, Mr. Paicely would receive a P-chem request form requesting a mass spectroscopy analysis of a particular chemical compound. A P-chem number that corresponded to the sample to be tested would be written on the P-chem request form. (EX 1158, ¶ 3).

F40. Mr. Paicely testifies that he recorded the following information in his log book: 1) the date the analysis was conducted; 2) the name of the chemist requesting the analysis; 3) the chemist's notebook page; 4) the chemist's suspected molecular weight; and 5) the measured molecular weight of the sample. (EX 1158, ¶ 4).

F41. According to Mr. Paicely, his log book demonstrates that he conducted a mass spectrometry analysis for P-chem request No. 469823 and lot No. C12-AMF-266. (EX 1158, ¶ 13). Mr. Paicely stated that his log notebook indicates that Mr. Cullinan was the chemist that requested the analysis. (EX 1158, ¶ 13).

F42. Mr. Paicely testifies that he conducted the mass spectroscopy analysis for PC request 469823. Mr. Paicely does not testify as to the results obtained from the analysis nor does Mr.

Paicely testify that the results of the analysis lead him to conclude that Mr. Cullinan had correctly identified the structure of the compound being tested.

F43. Mr. Paicely's declaration testimony states that on "March 7, 1993" he entered P-chem request No 469823 and lot No. C12-AMF-266. (EX 1158, ¶ 13). In contrast, P-chem request 469823 bears a notation of "23 March 93" under the heading "DATE SUB." (EX 1211, Bates No. 3071). Similarly, Mr. Cullinan testified that he submitted P-chem request 469823 for analysis on March 23, 1993. (EX 1152,¶ 38).

F44. Lilly has submitted redacted copies of pages 166 and 167 from Mr. Paicely's notebook. (EX 1231, Bates Nos. 3201 and 3202 respectively). Near the top of page 166 there is a notation that appears to be "25 March 1993." Near the middle of page 166 there appears to be the notation "26 March 1993." At the bottom of the page is the notation "7 Mar 93." Next to the "7 Mar 93" notation is the following "G. Cullinan R2A C12-AMF-266."

F45. Lilly states that a poor photocopy of Mr. Paicely's notebook page 166 resulted in the "27 Mar 93" date being cut off such that it reads "7 Mar 93." (Lilly Reply Brief, Paper No. 205, p. 13). Lilly, however, has not directed our attention to an accurate photocopy of the lab notebook page.

Biological Activity of Compound 311583

F46. Mr. David E. Magee is an Assistant Senior Biologist employed by Lilly. (EX 1156, ¶ 3). From 1992 to 1994 Mr. Magee worked in the *In Vivo* Pharmacology Laboratory of the Skeletal Research Division under the supervision of Dr. Henry Bryant, a named inventor of the involved '434 application. (EX 1156, ¶ 4).

F47. Mr. Magee testifies that he tested compound 311583 in a blood serum cholesterol assay between April 17-21, 1993. The protocol for the test is provided in Lilly Exhibit 1236, Bates No. 3222. Generally, the test compounds were administered to rats that were sacrificed and measurements, including blood serum cholesterol, were analyzed against a control group. (EX 1156, ¶ 13). Documentation regarding the test data is provided in Lilly Exhibit 1237, which indicates that dosing for a variety of compounds, including 311583, began on April 17 and ended on April 23, 1993. The chemist said to have requested the testing is listed as Mr. Cullinan. (EX 1237, Bates No. 3225).

F48. Mr. Magee states that compound 311583 resulted in a "significant reduction of serum cholesterol at the lowest dosage tested, 0.1 mg/kg, in the treated rats as compared to ovariectomized rats." (EX 1156, ¶ 16). Mr. Magee is said to have reported these results to Mr. Henry Bryant the week that the tests were performed. (EX 1156, ¶ 16). Further, these results were said to have been made available before the end of the week to the chemists in the Skeletal Research Division through a computer filing network. (EX 1156, ¶ 16).

F49. Mr. Magee's declaration testimony (EX 1156) does not specifically identify the structure of compound 311583. Moreover, Mr. Magee fails to specifically indicate that he was aware of the structural identity of compound 311583. Similarly, even if Mr. Magee was aware of the actual structure of the tested compound, Mr. Magee does not state the basis for such knowledge.

III. Opinion

Priority in an interference is awarded to the party establishing either (1) an earlier date of reduction to practice, or (2) an earlier date of conception, but a later date of reduction to practice, coupled with a reasonable diligence to a reduction to practice from (a) a time prior to the opponent's conception until (b) the party's reduction to practice is achieved. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000); *Mahurkar v. C. R. Bard, Inc.*, 79 F.3d 1572, 1577, 38 USPQ2d 1288, 1290 (Fed. Cir. 1996).

A party that is both first to conceive of the subject matter of the count and first to reduce it to practice is deemed the first to invent. *Eaton v. Evans*, 204 F.3d at 1097, 53 USPQ2d at 1698; *Hyatt v. Boone*, 146 F.3d 1348, 1351, 47 USPQ2d 1128, 1129 (Fed. Cir. 1998). A reduction to practice may be a "constructive reduction to practice" or an actual reduction to practice.

An actual reduction to practice is a question of law which is resolved on the basis of underlying facts. *Estee Lauder, Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592, 44 USPQ2d 1610, 1613 (Fed. Cir. 1997). Specifically, in an interference proceeding, a party seeking to establish an

actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment that met every requirement of the interference count, and (2) the embodiment operated for its intended purpose. *Eaton*, 204 F.3d at 1097, 53 USPQ2d at 1698. As to the second prong, there must there be some recognition of successful testing prior to the critical date for an invention to be reduced to practice. Thus, "a reduction to practice does not occur until an inventor, or perhaps his agent, knows that the invention will work for its intended purpose." *Estee Lauder, Inc.*, 129 F.3d at 593, 44 USPQ2d at 1614.

A rebuttable presumption exists that, as to each count, the inventors made their invention in the chronological order of their effective filing dates. The burden of proof shall be upon a party who contends otherwise. 37 CFR § 1.657(a).

In an interference between two copending applications, such as this, the junior party has the burden of proof to establish priority and that burden is by a preponderance of the evidence. 37 CFR § 1.657(b). The burden of showing something by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Products of California, Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 622, 113 S. Ct. 2264, 2279 (1993). This ultimate burden of proof always remains with the junior party in the interference. *Brown v. Barbacid*, 276 F.3d 1327, 1333, 61 USPQ2d 1236, 1239 (Fed. Cir. 2002).

Cameron is the senior party based upon its accorded priority date of October 12, 1993. Lilly is the junior party based upon its accorded priority date of September 20, 1994. As junior

party, Lilly does not allege an earlier conception coupled with diligence to its later constructive reduction to practice of September 20, 1994. Rather, Lilly alleges an earlier actual reduction to practice.

As discussed above, Lilly has submitted numerous alleged reductions to practice that are said to fall within the scope of the count. (See, Paper No. 202, Appendix B1 "Examples of compounds made by Dave Jones that fall within the scope of Count 2," and Appendix B2 "Examples of Compounds made, used or manipulated by other named inventors of the Lilly Application that fall within the scope of Count 2 "). While Lilly has submitted evidence regarding the alleged conception and manufacture for many of these compounds, Lilly has failed to sufficiently demonstrate that at least one of the inventors understood that the various compounds worked for their intended purpose. Specifically, with the exception of Lilly Compounds 311583 and 125001, Lilly has failed to sufficiently identify evidence that the allegedly manufactured compounds were tested to establish a practical, recognized utility. For example, under the argument section of Lilly's Main Brief at Final Hearing there is only one heading directed to the usefulness of the allegedly manufactured compounds. (Paper No. 202, p. iii, heading no. VI. 6.). Moreover, this "usefulness" section merely details Mr. Magee's analysis of Lilly Compound No. 311583 and does not mention the testing of compound 125001 or any other allegedly manufactured compound. (Paper No. 202, pp. 37-38).

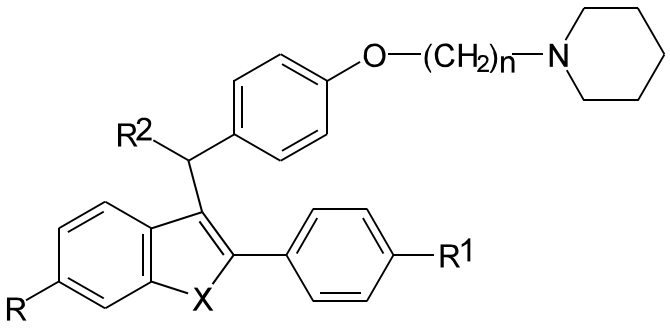
As to compound 125001, Lilly has failed to direct our attention to the specific structure of the compound. As such, we focus our attention on Lilly compound 311583 as Lilly has alleged

that: 1) Compound 311583 is encompassed by Count 2; and 2) at least one named inventor recognized that the 311583 compound worked for its intended purpose.

A. Actual Reduction to Practice of Lilly Compound Serial No. 311583

Lilly alleges that it is entitled to an award of priority as Lilly allegedly was the first to conceive of and the first to reduce the invention of the Count to practice. (Paper No. 205, p. 1). Cameron does not appear to dispute Lilly's contention that Lilly conceived of a compound falling within the scope of the count prior to Cameron. Cameron, however, contends that Lilly's has failed to demonstrate a prior actual reduction to practice.

The facts regarding Lilly's alleged reduction to practice for compound 311583 are discussed in detail under the fact section provided above. Generally, Lilly states that Dr. Jones, suggested that Mr. Cullinan investigate a compound having the structure:



wherein R^1 is -OH, R^2 is -H, n is two and X is sulfur. (Paper No. 202, p. 25). Both Dr. Jones and Mr. Cullinan are named inventors for Lilly's involved '434 application.

According to Lilly, Mr. Cullinan conducted various reduction reactions. Generally, Lilly directs our attention to Mr. Cullinan's alleged reduction reactions of June 2, 1992 and March 11, 1993. (Lilly Main Brief at Final Hearing, Paper No. 202, pp 26-31). Further, Lilly directs our attention to Mr. Cullinan's March 17, 1993 salifying process for the product obtained on page 261 of his notebook (the product made on March 11, 1993) and his March 22, 1993 process for drying the March 17, 1993 salified product. (Paper No. 202, pp. 32-35). Lilly contends that the products made by Mr. Cullinan on June 2, 1992, March 11, 1993, March 17, 1993 and the dried product made on March 22, 1993 fall within the scope of Count 1.

Between April 17 and April 21, 1993, a Lilly scientist, Mr. Magee, is said to have performed an analysis of the biological activity of a variety of compounds, including Mr. Cullinan's March 17, 1993 product identified as compound no. LY 311583. (Paper No. 202, p. 38). Mr. Magee is said to have observed that LY 311583 did induce a significant reduction of serum cholesterol at the lowest dosage tested, 0.1 mg/kg, in the treated rats as compared to control rats. Mr. Magee is said to have reported these results to a Lilly named inventor, Mr. Henry Bryant, in the week in which the tests were performed. (Paper No. 202, p. 38).

Cameron argues that Lilly has failed to prove an actual reduction to practice. Specifically, Cameron alleges that Lilly lacks sufficient corroborated evidence of an actual reduction to practice. (Paper No. 203, p. 10). Cameron states that, with the exception of the mass spectroscopy testimony of Mr. Paicely, the alleged analytical data is not supported by testimony of the persons who actually did the testing. Moreover, Cameron states that there is no explanation of how any analytical data, including that allegedly generated by Mr. Paicely,

confirms the structure of Mr. Cullinan's reaction product. (*Id*.). Indeed, Cameron questions how Lilly, and more particularly Mr. Cullinan, confirmed that Mr. Cullinan produced the compound identified as Lilly 311583. (*Id*.)

An inventor's testimonial assertions of inventive facts must be corroborated by independent evidence. As stated by the Federal Circuit:

> This court applies a "rule of reason" analysis to determine sufficient corroboration. In applying the "rule of reason" test, this court examines "all pertinent evidence" to determine the credibility of the "inventor's story." This "rule of reason" analysis does not alter the requirement of corroboration for an inventor's testimony. The inventive facts must not rest alone on testimonial evidence from the inventor himself. As stated in *Hahn*, 892 F.2d at 1032, "[t]he inventor ... must provide independent corroborating evidence in addition to his own statements and documents."

Brown v. Barbacid , 276 F.3d at 1335, 61 USPQ2d at 1240 (citations omitted).

According to Lilly, corroboration of the actual reduction to practice is provided by the following:[3]

1. Documentary evidence, for example, a corresponding notebook page, a request for physical chemistry analysis and/or a request for a Lilly serial number.
2. Testimonial evidence of Clifford Paicely
3. Testimonial evidence of Susan M. Sharples
4. Testimonial evidence of Mr. F. William Bell
5. Testimonial evidence of Mr. David E. Magee

(Lilly Reply Brief at Final Hearing, Paper No. 205, pp. 8-9). The sufficiency of Lilly's alleged corroborative evidence is discussed below.

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[3]Lilly also identified the testimony of Mr. Bennie Foster (LX 1051) and Mr. Robert W. Brickley (LX 1157). Their testimony does not specifically relate to the compound identified as LY 311583 for which Lilly has produced evidence of utility.

1. Lilly's Documentary Evidence Fails to Demonstrate Sufficient Corroboration that Mr. Cullinan Manufactured a Compound Having the LY 311583 Structure

Lilly has presented alleged documentary evidence of an actual reduction to practice for Lilly's compound LY 311583. The evidence, however, is primarily the inventor's own documents. Specifically, Lilly directs our attention to the inventor's notebook pages, the inventor's request for physical chemistry ("PC") laboratory analysis as well as the inventor's request for a Lilly serial number. (Paper No. 205, p. 8). An inventor's own unwitnessed documentation, however, does not necessarily corroborate an inventor's testimony about inventive facts. *Id*.

Rule 37 C.F.R. §1.671(f) provides that the significance of documentary and other evidence identified by a witness in an affidavit shall be discussed with particularity. We note that Mr. Cullinan's laboratory notebook pages and PC analysis requests contain notations apparently indicating that various tests were run on the products Mr. Cullinan is said to have made. Yet, both Lilly and Mr. Cullinan have failed to explain the source of the various notations or the meaning of the notations.

As to the source material for the notations, Lilly has failed to explain whether the notations were taken directly from the "printout of the results in the test(s) conducted" or whether they represent Mr. Cullinan's uncorroborated interpretation of the results. (See, LX 1152, ¶ 23). As to the meaning of the notations contained in the notebook pages and PC requests, Lilly has failed to sufficiently explain how they "confirm" that Mr. Cullinan made a compound having the structure identified as compound 311583. For example, page 266 of Mr. Cullinan's notebook

contains notations that would appear to be elemental analysis results. Yet, Lilly has failed to explain how the elemental analysis notations in his notebook demonstrate that Mr. Cullinan produced the LY 311583 compound structure as opposed to a different compound having the same empirical formula. Indeed, Lilly has failed to explain the "calc" values and the "fd" values listed on page 266 of Mr. Cullinan's notebook.

Our review of the underlying documents fails to persuade us that it is more probable than not that Mr. Cullinan correctly identified that structure of the compounds he manufactured. For example, Mr. Cullinan testified that on March 23, 1993 he submitted the product from the further preparation of the compound described on p. 266 of his notebook for mass spectroscopy analysis and elemental analysis under request PC 469,823. (LX 1152, ¶ 38). Mr. Cullinan states that the mass spectroscopy and elemental analysis helped to confirm that he made a compound falling within the scope of Count 2. PC request 469,823 contains the notation "496.07" under the heading "Approx. M.W."[4] and also "M.S. mw=460 FD" under a heading "CONDITIONS." Based upon our informal calculations, the HCl structure depicted on PC request 469,823 should have a molecular weight of approximately 496 and the unsalified structure (no HCl) should have a molecular weight of approximately 460. Mr. Cullinan, however, fails to explain why the request lists "mw=460" for the depicted HCl structure. While Mr. Cullinan and Lilly could and should have explained such notations, they did not.

Additionally, several of Mr. Cullinan's PC requests contain notations that appear to be the first name of an analyst who presumably would have conducted the tests requested. (See,

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[4]We assume that the notation "Approx. M.W." refers to approximate molecular weight.

e.g., LX 1211, PC Requests 469590 "Rose"(?) and 469823 "Ray"). Lilly has not directed our attention to the testimony of these potential analysts.

2. Mr. Clifford Paicely's Testimony Does Not Identify the Structure of the Tested Compound

Clifford Paicely has testified that he has been continuously employed at Lilly as a Senior Laboratory Technician since 1981. (EX 1158, ¶ 2). Mr. Paicely testified that his log book demonstrates that he conducted a mass spectrometry analysis for P-chem request No. 469823 and lot No. C12-AMF-266. (EX 1158, ¶ 13). Mr. Paicely stated that his log notebook indicates that Mr. Cullinan was the chemist that requested the analysis. (EX 1158, ¶ 13).

Mr. Paicely's declaration testimony states that on "March 7, 1993" he entered P-chem request No. 469823 and lot No. C12-AMF-266. (EX 1158, ¶ 13). Yet, P-chem request 469823 bears a notation of "23 March 93" under the heading "DATE SUB." (EX 1211, Bates No. 3071). Similarly, Mr. Cullinan testified that he submitted P-chem request 469823 for analysis on March 23, 1993. (EX 1152,¶ 38). Lilly explains this discrepancy as the result of a poor photocopy of Mr. Paicely's notebook page. Specifically, Lilly states that the poor photocopy resulted in the "27 Mar 93" date being cut off such that it reads "7 Mar 93." (Lilly Reply Brief, Paper No. 205, p. 13). From Lilly's explanation of the error, we conclude that Mr. Paicely does not independently recall the testing of Mr. Cullinan's sample. Rather, Mr. Paicely's testimony is an explanation of the notations listed in Mr. Paicely's notebook.

Mr. Paicely's testimony and notebook do not provide the results of the mass spectroscopy test conducted for Mr. Cullinan. Furthermore, neither the notebook nor Mr. Paicely's testimony indicate that Mr. Cullinan had correctly identified the structure of the compound sent for testing.

3. Susan M. Sharples' Testimony Does Not Confirm the Identity of the Compounds Allegedly Made by Mr. Cullinan

Ms. Susan M. Sharples is a Physical Chemist employed by Lilly. (EX 1160, ¶ 2). Ms. Sharples testified that the physical chemistry submission sheet requests 469307, 469590 and 469823 are true and accurate copies of those contained in Physical Chemistry microfilm archives. (EX 1160, ¶ 6).

Ms. Sharples' testimony helps verify that Lilly's P-Chem requests presented into evidence are true and accurate copies of those contained in Lilly's P-Chem Laboratory microfilm archives. Her testimony does not comment upon the accuracy of the information contained within those requests. In particular, Ms. Sharples' testimony fails to confirm that Mr. Cullinan manufactured a compound having the structure depicted as Lilly compound 311583.

4. Mr. F. William Bell's Testimony Does Not Confirm the Identity of the Compounds Allegedly Made by Mr. Cullinan

Mr. F. William Bell is an Assistant Senior Chemist at Lilly. (EX 1159, ¶ 2). Mr. Bell testified that the 311583 submission sheet (LX 1216, Bates No. 3114) presented into evidence is a true and accurate copy of the one he obtained from Lilly's Research Records. (EX 1159, ¶ 7).

Mr. Bell's testimony verifies that Lilly's 311583 submission sheet is a true and accurate copy of that contained in Lilly's Research Records microfilm archive. Mr. Bell's testimony, however, does not comment upon the accuracy of the information contained within the 311583 submission sheet. In particular, Mr. Bell's testimony fails to confirm that Mr. Cullinan manufactured a compound having the structure depicted as Lilly compound 311583.

5. Mr. Magee's Testimony Does Not Confirm the Identity of the Compounds Allegedly Made by Mr. Cullinan

Mr. Magee testified that during the period of 1992 to 1994 he was an Associate Biologist working in the In Vivo Pharmacology Laboratory of the Lilly's Skeletal Research Division. (Declaration of David E. Magee, EX 1156, ¶ 4). Mr. Magee testified that between August 22-26, 1992, the lab conducted an analysis of the biological activity of various compounds, including a compound with serial number LY 125001. Further, Mr. Magee testified that between April 17-21, 1993, he performed an analysis of the biological activity of compounds, including a compound with serial number LY 311583.

Mr. Magee's testimony fails to identify the structure and chemical make-up of the tested compounds. As such, Mr. Magee's testimony fails to confirm that Mr. Cullinan manufactured a compound having the structure depicted as Lilly compound 311583.

B. Lilly Failed to Provide Sufficient Evidence of an Actual Reduction to Practice

Lilly, as junior party, has the burden of proof to establish priority and that burden is by a preponderance of the evidence. Lilly has failed to meet that burden.

Lilly has attempted to demonstrate that it was first to conceive and first to reduce to practice an invention falling within the scope of the Count. Cameron does not appear to contest that Lilly was first to conceive of an embodiment falling within the scope of the Count. Based on the evidence presented, we conclude that Lilly was the first to conceive of a compound falling within the scope of Count 2, the sole count in interference. Yet, we also conclude that Lilly has failed to sufficiently demonstrate an actual reduction to practice of a compound falling within the scope of Count 2.

Lilly has apparently attempted to identify and confirm a practical utility for only one specific compound, LY 311583. As to that compound, Lilly has failed to sufficiently demonstrate that Mr. Cullinan actually prepared a compound having the structure depicted in Lilly submission LY 311583. Specifically, Lilly has relied extensively upon information received from a named inventor, Mr. George J. Cullinan.

Mr. Cullinan has generally testified that he requested certain types of physical chemistry analyses of the compounds he produced. Without identifying or explaining the raw data produced from these chemical analyses, Mr. Cullinan has merely stated that the analyses "helped me to confirm whether I had obtained the desired product." (See, LX 1152, ¶ 23). We have not been directed to evidence that indicates that the chemical analyses were sufficient to confirm that LY 311583 had the postulated structure.

The question of whether or not Mr. Cullinan actually produced the desired compound is an inventive fact. An inventive fact must not rest alone on testimonial evidence from the inventor himself. *Brown v. Barbacid*, 276 F.3d at 1335, 61 USPQ2d at 1240; *Cooper v.*

Goldfarb, 154 F.3d 1321, 1330, 47 USPQ2d 1896, 1903-1904 (Fed. Cir. 1998). Mr. Cullinan's conclusions and the documents cited by Mr. Cullinan are not sufficiently corroborated to confirm the formation of a compound having the postulated structure. Specifically, Mr. Cullinan's testimony and the documents provided by Lilly fail to demonstrate a corroborated actual reduction to practice for an embodiment falling within the scope of the Count. Looking at all the corroborating evidence as a whole, using a rule of reason analysis, we conclude that Lilly has failed to sufficiently corroborate that LY 311583 had a structure falling within the scope of Count 2. As such, Lilly has failed to meet its burden of proof. Priority of invention for Count 2, the sole count in interference, is awarded against junior party Lilly.

IV. Judgment

Upon consideration of the record, it is:

ORDERED that priority of invention as to Count 2, the sole count in interference, is awarded against junior party Lilly.

FURTHER ORDERED that Lilly is not entitled to a patent containing claims 1-7, 21-22, 46, 50 and 54 of Lilly, U.S. Application No. 08/508,434.

FURTHER ORDERED that a copy of this decision shall be placed and given a paper number in Lilly, U.S. Application No. 08/508,434 and Cameron, U.S. Application No. 08/628,605.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

RICHARD E. SCHAFER)
Administrative Patent Judge)
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) BOARD OF PATENT
SALLY GARDINER-LANE) APPEALS
Administrative Patent Judge) AND
) INTERFERENCES
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)
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